5.0 510(K) SUMMARY

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Applicant Name:

M. Heather Cameron
Regulatory Compliance Specialist
Fisher Diagnostics
8365 Valley Pike
P.O. Box 307
Middletown, VA 22645
Phone: 540.869.8163
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Establishment Registration Number: 1181121

Identification of Device:

Proprietary/Trade Name: ARCHITECT® Anti-TPO Immunoassay, ARCHITECT® Anti-TPO Calibrators & Controls
Common Name: Anti-TPO test system
Device Name: ARCHITECT® Anti-TPO Immunoassay, ARCHITECT® Anti-TPO Calibrators & Controls
Device Classification: Class II
Governing Regulation: 21 CFR 866.5870, 862.1660, 862.1150
FDA Panel: Immunology, Clinical Chemistry
Product Code: JZO, JJX, JIT

Identification of Predicate Device:

Abbott AxSYM® anti-Thyroid peroxidase (Anti-TPO) Microparticle Enzyme Immunoassay (MEIA) (K020348)

Intended Use of the Device:

ARCHITECT® Anti-TPO is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma (EDTA and Heparin) on the ARCHITECT® i System. The ARCHITECT® Anti-TPO assay is intended for use as an aid in the diagnosis of autoimmune thyroid disease.

The ARCHITECT® Anti-TPO Calibrators are for the calibration of the ARCHITECT® *i* System when used for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma.

The ARCHITECT® Anti-TPO Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT® *i* System (reagents, calibrators and instrument), when used for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma.

Description of the Device:

The ARCHITECT Anti-TPO assay is a two-step immunoassay for the quantitative determination of anti-TPO in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®.
In the first step, sample, assay diluent and TPO coated paramagnetic microparticles are combined and incubated. Anti-TPO present in the sample binds to the TPO coated microparticles. After washing, anti-human IgG acridinium labeled conjugate is added in the second step. Following another incubation and wash, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLU). A direct relationship exists between the amount of anti-TPO in the sample and the RLUs detected by the ARCHITECT *i* system optics.

Comparison of Technological Characteristics:

The ARCHITECT® Anti-TPO assay and the Abbott AxSYM® anti-Thyroid peroxidase (Anti-TPO) Microparticle Enzyme Immunoassay (MEIA) use a microparticle immunoassay method for the quantitative determination of Anti-TPO in human serum or plasma. Both assays have TPO coated microparticles.

Summary of Non-Clinical Performance:

The ARCHITECT® Anti-TPO assay is substantially equivalent to the Abbott AxSYM® anti-Thyroid peroxidase (Anti-TPO) Microparticle Enzyme Immunoassay (MEIA) in terms of precision, linearity, interferences, and stability as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT Anti-TPO assay demonstrated substantially equivalent performance to the Abbott AxSYM® anti-Thyroid peroxidase (Anti-TPO) Microparticle Enzyme Immunoassay (MEIA). A method concordance using the NCCLS Standard (EP-12A) was also conducted with the ARCHITECT Anti-TPO assay and Abbott AxSYM® anti-Thyroid peroxidase (Anti-TPO) Microparticle Enzyme Immunoassay (MEIA) and as a result, the two systems demonstrated substantial equivalence as indicated by clinical data in this 510(k) submission (92.6% Concordance).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 18 2006

Fisher Diagnostics
c/o Ms. Heather Cameron
Regulatory Compliance Specialist
8365 Valley Pike
P.O. Box 307
Middletown, VA 22645

Re: k052407
Trade/Device Name: ARCHITECT® Anti-TPO Immunoassay and ARCHITECT® Anti-TPO Calibrators and Controls
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO, JJX, JIT
Dated: August 31, 2005
Received: September 2, 2005

Dear Ms. Cameron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510 (k) Number (if known): K052407/S1

Device Name: ARCHITECT® Anti-TPO Immunoassay, ARCHITECT® Anti-TPO Calibrators & Controls

Indications for use:

Reagent Intended Use:
ARCHITECT® Anti-TPO is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma (EDTA and Heparin) on the ARCHITECT® i System. The ARCHITECT® Anti-TPO assay is intended for use as an aid in the diagnosis of autoimmune thyroid disease.

Calibrators Intended Use:
The ARCHITECT® Anti-TPO Calibrators are for the calibration of the ARCHITECT® *i* System when used for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma.

Controls Intended Use:
The ARCHITECT® Anti-TPO Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT® *i* System (reagents, calibrators and instrument), when used for the quantitative determination of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum and plasma.

Prescription Use (Part 21 CFR 801 Subpart D) x AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052407